IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01362 Hon. David A. Faber
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01665 Hon. David A. Faber

REPLY MEMORANDUM IN SUPPORT OF MCKESSON'S MOTION FOR JUDGMENT ON PARTIAL FINDINGS REGARDING ACTIONABLE CONDUCT

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INTRODUCTION

Plaintiffs' Opposition confirms that McKesson is entitled to judgment under Rule 52(c). Plaintiffs do not dispute that they must actually link their claims of wrongdoing to the harm they allege by proving—at a minimum—that McKesson's shipments to its pharmacy customers in Cabell/Huntington were unreasonable, and that those unreasonable shipments were a substantial factor in bringing about the opioid crisis in Cabell/Huntington. *See* Opp. at 30.[1] The Opposition makes clear that Plaintiffs cannot meet that burden.

Plaintiffs do not contest that McKesson's Cabell/Huntington retail pharmacy market share was only 6% or that McKesson has only ever had a small handful of pharmacy customers in Cabell/Huntington. Thus, Plaintiffs need (at the least) some evidence that McKesson's alleged suspicious order monitoring ("SOM") failures (1) resulted in improper shipments to customers in Cabell/Huntington, and (2) that the pharmacy customers who received those shipments were engaged in improper dispensing—*i.e.*, were facilitating diversion.[2] But Plaintiffs have no evidence on either score. Their Opposition largely concedes the point, only even discussing two McKesson-serviced pharmacies in Cabell/Huntington. And nothing they say about either pharmacy establishes unreasonable conduct on the part of McKesson—let alone a substantial contribution to Cabell/Huntington's opioid problems. *See infra* Part I.

[1] For purposes of this motion, McKesson assumes that Plaintiffs are correct that the applicable standard is one of unreasonable conduct. Mem. at 4–5.

[2] As explained elsewhere, wholesale distributors like McKesson have neither the ability nor any duty to prevent "medicine cabinet diversion," which occurs only after prescription opioids have left the closed system of distribution and have been dispensed to a patient pursuant to a legitimate prescription written by a doctor. *See* Defs' Mem. in Support of J. on Partial Findings Related to Proximate Causation (ECF No. 1440) at 24–28. Accordingly, in order to establish liability on the part of McKesson, Plaintiffs would need to prove (at a minimum) that the medicines it distributed to its pharmacy customers were improperly dispensed *by that pharmacy customer*.

Instead, Plaintiffs attempt to avoid their burden by making three other arguments. *First*, Plaintiffs assert that the "overall volume" of McKesson's shipments into Cabell/Huntington were problematic. But ***no record evidence*** supports Plaintiffs' argument that distribution volumes alone can establish unreasonableness. This is especially clear in the case of McKesson, whose distribution volumes into Cabell/Huntington were substantially lower than several non-present distributors and substantially lower than the statewide and national averages that Plaintiffs otherwise rely on as evidence of wrongdoing. *See infra* Part I.

Second, Plaintiffs point to McKesson pharmacy customers located outside of Cabell/Huntington and suggest that McKesson's shipments to those pharmacies were unreasonable. As an initial matter, Plaintiffs' evidence does not support that assertion. But, more fundamentally, Plaintiffs have utterly failed to come forward with evidence establishing a "substantial nexus" between McKesson's distributions to those extra-territorial pharmacies and any diversion in Cabell/Huntington. Thus, Plaintiffs have failed to show that those distributions were a substantial factor in causing the opioid crisis ***in Cabell/Huntington***. *See infra* Part II.

Third, Plaintiffs point to generalized "evidence"—typically in the form of not-yet-admitted or previously excluded documents that were not the subject of any live trial testimony—of alleged failures in McKesson's SOM programs. Here, too, Plaintiffs' evidence fails on its own terms. But, even more crucially, it is all totally irrelevant. The Court need not, for instance, determine whether McKesson's systems for reporting suspicious orders were always perfect in order to enter judgment in its favor. Rather, the ultimate question before this Court is whether McKesson's conduct caused the diversion of prescription opioid medicines ***in Cabell/Huntington***. If it did not (and there is no evidence that it did), then McKesson's alleged SOM failures could not have

contributed in any meaningful way to the alleged ongoing public nuisance in Cabell/Huntington that Plaintiffs seek to abate. *See infra* Part III.

ARGUMENT

I. PLAINTIFFS CANNOT SHOW UNREASONABLE CONDUCT BY MCKESSON THAT WAS A SUBSTANTIAL FACTOR IN CAUSING DIVERSION IN CABELL/HUNTINGTON.

The record is devoid of evidence of diversion occurring at any McKesson-serviced pharmacy in Cabell/Huntington. Faced with this complete and independently dispositive failure of proof, Plaintiffs argue—without citation to any record evidence—that certain shipment volumes were "simply too high to be used exclusively for legitimate purposes." Opp. at 18. Plaintiffs are wrong. There is no evidence supporting Plaintiffs' argument that McKesson's specific volume of shipments, without more, can establish wrongdoing. *See* Defs.' Reply Mem. in Support of J. on Partial Findings Regarding Proximate Causation at 21–22 ("Defs.' Proximate Causation Reply").[3] And, for the reasons explained below, there is no other evidence that McKesson's distributions into Cabell/Huntington were unreasonable or that any of McKesson's pharmacy customers in Cabell/Huntington were engaged in diversion.

As established in McKesson's opening brief, the vast majority of McKesson's shipments in Cabell/Huntington—over 76%—went to the Veterans Affairs Medical Center ("V.A. Medical Center"). Mem. at 7–8. Plaintiffs have disavowed any claim that McKesson's shipments to the V.A. Medical Center were unlawful or otherwise actionable, and Plaintiffs' DEA expert opined

[3] Plaintiffs cite testimony from Mr. Rannazzisi purportedly suggesting that "distributors should consider the volume of opioids it [sic] sells to a customer or area relative to its population," Opp. at 32 & n.142, but the cited testimony says no such thing. Rather, it says only that distributors should identify "anomalies within the[] ordering patterns" of their customers, *i.e.*, pharmacies. *See* 6/8 Trial Tr. (Rannazzisi) at 186:1–24.

that those shipments were not "applicable to the diversion topic." 5/26 Tr. (Rafalski) at 271:24–272:6. As to the V.A. shipments, those concessions are dispositive.[4]

Setting aside McKesson's shipments to the V.A. (as Plaintiffs concede is appropriate[5]), the record shows that McKesson's shipments of opioid medicines into Cabell/Huntington were too small to be a substantial factor in causing the opioid abuse problem in Cabell/Huntington. Plaintiffs do not dispute that (1) McKesson's total share of the retail pharmacy market in Cabell/Huntington was just 6 percent, or (2) five other wholesale distributors delivered more opioid medicines to Cabell/Huntington than did McKesson. Nor do they dispute that McKesson's shipments into Cabell/Huntington were ***substantially lower*** than the corresponding statewide and national averages. Mem. at 8; Trial Ex. P-44711 at 25 (McKesson's per capita distribution rates). Given that Plaintiffs' own theory of liability is built almost entirely upon comparisons of each Defendant's distributions into Cabell/Huntington with these very statewide and national averages, the undisputed fact that McKesson's shipments were 45% and 15% lower than the averages on which Plaintiffs rely is fatal. 5/11 Tr. (McCann) at 176:25–177:19.

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[4] During closing arguments, the Court asked why shipments to the V.A. would be different from shipments to McKesson's retail pharmacy customers. The principal difference is that the individuals prescribing and dispensing prescription opioids are federal government employees, whose decisions are overseen, directed, and approved by the United States. Accordingly, there are especially good reasons to believe that the V.A. facility is not a significant source of improper prescribing or dispensing. Furthermore, Plaintiffs presented absolutely no evidence of any improper V.A. activity—the record is entirely silent on that issue.

To be sure, where "medicine cabinet diversion" is concerned, the V.A. facility is not different. Medicines legitimately prescribed and dispensed by the V.A. can later be diverted by patients or third parties in the same manner as pills dispensed by retail pharmacies. However, as explained elsewhere, Defendants have neither the ability nor a duty to prevent such "medicine cabinet diversion." *See supra* n.2.

[5] While purporting to exclude shipments to the V.A. Medical Center, Plaintiffs repeatedly emphasized during closing argument that pharmacies in Cabell/Huntington received approximately 81 million dosage units over more than a decade. Plaintiffs did not disclose that over 17.6 million of those doses—more than 20%—were shipments to the V.A. Medical Center that they have affirmatively disclaimed. 5/10 Tr. at 87:8–11, 91:2–8.

Plaintiffs' only response to any of these arguments is their assertion that McKesson's six percent "market share is substantially greater than those found by the MDL Court to be more than *de minimis*." Pls.' Mem. in Opp. to Defs.' Mot. for J. on Partial Findings on Causation (ECF No. 1469) at 42 n.7. The cited MDL decision, however, held only that the moving defendants were not entitled to judgment on a motion to dismiss because there was a "contested issue of fact that must be resolved by the trier of fact." *E.g.*, MDL ECF No. 2559 at 5. By contrast, this Court is now tasked—as the finder of fact—with determining whether McKesson's tiny share of the overall market for prescription opioids in Cabell/Huntington can be treated as a cause of the opioid crisis in those communities—a question which no prior decision has purported to answer. Especially where, as here, the record contains no evidence of any wrongdoing or diversion at any of the small number of pharmacies serviced by McKesson, Plaintiffs simply have not met their burden of proof.

As described in its opening brief, McKesson has had roughly three pharmacy customers in Cabell/Huntington at any one time. Even more tellingly, Plaintiffs' own brief only even bothers to discuss two of those pharmacies—Rite Aid #968 and Custom Script. As to those customers, Plaintiffs do not come forward with any evidence of diversion, "oversupply," or any other allegedly actionable conduct.

Rite Aid. Plaintiffs suggest that McKesson's shipments to one particular Rite Aid store—Rite Aid #968—were "problematic," *see* Opp. at 19, but they fail to present any record evidence that Rite Aid #968 was engaged in any improper dispensing—let alone that McKesson knew or should have known about any such dispensing.

First, Plaintiffs entirely ignore the only record evidence relating to the conduct of Rite Aid #968. The record reveals that the pharmacy was inspected by the West Virginia Board of Pharmacy ("BOP") on four separate occasions—in 2005, 2011, 2015, and 2017—and that, upon

each inspection, the BOP concluded that "all prescriptions appear prescribed for a legitimate purpose." Trial Ex. DEF-WV-01989 at 5 (question 57), 19 (question 58), 38 (question 43), 87 (question 11); *see also* 5/27 Tr. (Rafalski) at 21:7–25:23. The Board of Pharmacy further concluded that Rite Aid #968 was a "GOOD PHARMACY!" Trial Ex. DEF-WV-01989 at 20. Plaintiffs' SOM expert, James Rafalski, acknowledged that he did not "have any contrary facts about this pharmacy or any Rite-Aid in Cabell/Huntington." 5/7 Tr. at 26:7–9. And Plaintiffs cite none in their brief.

Second, Plaintiffs' assertion that McKesson's distributions to Rite Aid #968 were "over 1.5 times McKesson's national, West Virginia, and Cabell/Huntington averages," Opp. at 19, does not provide any basis for concluding that McKesson's shipments to the store were unreasonable. As Defendants have explained, there is no record evidence supporting Plaintiffs' assertion that such comparisons alone can establish unreasonableness or a violation of the Controlled Substances Act ("CSA"). *See* Defs.' Proximate Causation Reply at 21–22. Indeed, Plaintiffs' assertion defies basic mathematical logic, as any ***average*** is necessarily derived from a set of numbers both above and below that average.

Even accepting Plaintiffs' erroneous contention that such comparisons to statewide and national averages could ever be meaningful, the suggestion that a deviation of 50% is indicative of wrongdoing makes no sense. A divergence of only 50% does not show that Rite Aid #968 is an outlier; it merely shows that it is a little bit above average. Just as it would not be at all surprising that a baseball team with a .220 average has a player hitting .330, there is nothing remotely surprising or problematic about the fact of a pharmacy ordering 50% more prescription opioids than average. In short, the fact that Rite Aid #968 ordered 1.5 times more prescription opioids than McKesson's average customer proves exactly nothing.

Third, Plaintiffs' assertions that (i) Rite Aid thresholds "were set too high," Opp. at 18, and (ii) McKesson did not perform "sufficient due diligence" before "increasing thresholds" for Rite Aid stores," Opp. at 11, are unavailing.

Neither Mr. Rafalski nor any other trial witness ever testified that McKesson's thresholds were set too high—for Rite Aid or any other McKesson customer. The only evidence Plaintiffs cite to support their assertion is an email that makes reference to use of a "buffer" in setting certain thresholds. Opp. at 18 n.82 (citing Trial Ex. P-12967).[6] But Mr. Oriente, McKesson's Director of Regulatory Affairs, explained that "buffers" were used as a reasonable measure to "offset … variability where pharmacies order more or less each month." 5/25 Tr. at 103:17–19. Plaintiffs point to no evidence establishing that the use of buffers to account for ordering variability was unreasonable.[7]

Plaintiffs' related assertion that Rite Aid #968 received a higher buffer than some other customers, *see* Opp. at 7 n.29, is both irrelevant and incorrect. The testimony Plaintiffs cite shows only that, when Mr. Oriente was asked about an alleged 30% "buffer" for Rite Aid stores, he clarified "that's not correct" because "[n]ot all Rite Aids received … the additional buffer." 5/24 Tr. (Oriente) at 129:6–20. There is no record evidence that Rite Aid #968 had a 30% "buffer." Rather, the only record evidence on this point is that McKesson told the DEA that its "thresholds

[6] Plaintiffs cite a number of additional documents, *see* Opp. at 7 n.29, but each relates to an instance where McKesson was *reducing* thresholds based on proactive reviews of customer ordering. *See* Trial Exs. P-08309 (suggestion of "reduc[ing] some of the thresholds"), P-08247 ("Threshold Reduction Report"); P-13211 ("Review & Threshold Reductions"); P-13212 (review done "to adjust select based code thresholds downward").

[7] Plaintiffs' claim that Rite Aid thresholds were "automatically" increased falls equally short, as the testimony Plaintiffs cite shows precisely the opposite. *Compare* Opp. at 18 n.84 (citing 5/24 Tr. (Oriente) at 169–170)), *with* 5/24 Tr. (Oriente) at 169:10–170:12 (testifying that threshold increases for Rite Aid were considered only "when they were requested" and that prior to "[t]he increase would have been reviewed" prior to being granted only "for a specific CII that [Rite Aid] would have requested").

would be based on a customer's history with a buffer," and the DEA did not object to that practice. 5/25 Tr. (Oriente) at 104:2–7; Trial Ex. P-42657 at 8.

Plaintiffs' reliance on testimony from Mr. Rafalski regarding the supposed absence of "evidence in the record" that McKesson was performing "sufficient due diligence of the Rite Aid stores in Cabell-Huntington" is likewise misplaced. *See* Opp. at 11. As an initial matter, Mr. Rafalski acknowledged that there is no required retention period for diligence materials, such that the supposedly nonexistent records may simply not have been retained long enough to become part of the discovery record. *See infra* pp. 11–12. Moreover, as Mr. Oriente explained, McKesson's due diligence for retail chain pharmacies differed because the chains had "their own Regulatory Department[s]," such that McKesson would partner "with their corporate office on any reviews"—a practice that McKesson disclosed to DEA without objection. 5/25 Tr. 106:4–23, 141:1–24.

Finally, Plaintiffs have no evidence of any diversion or other issue occurring at Rite Aid #968 (or any Rite Aid in Cabell/Huntington). As noted above, the evidence in fact shows the opposite—that it was a "GOOD PHARMACY!" *See supra* p. 6. But even assuming that Plaintiffs could prove that McKesson's shipments to Rite Aid #968 were unreasonable (they cannot) or that McKesson's systems for monitoring retail national accounts like Rite Aid were less than perfect, that still would not show diversion. And, absent evidence of diversion occurring at a Rite Aid store in Cabell/Huntington, Plaintiffs could not possibly show that McKesson's shipments to that store were a substantial factor in causing the harms underlying Plaintiffs' claims.

Plaintiffs' only response is to point to the testimony of Mr. Rafalski that "it was more likely than not that flagged orders regarding which McKesson did not conduct due diligence would be diverted." Opp. at 11. For the reasons explained in Defendants' Reply Brief in Support of

Judgment on Partial Findings Regarding Proximate Causation, the Court should not credit Mr. Rafalski's implausible and unsupported flagging opinions or his *ipse dixit* diversion opinion. *See* Defs.' Proximate Causation Reply at 28–32. In any event, three critical concessions preclude the Court from relying on Mr. Rafalski to conclude that diversion occurring at Rite Aid #968 was a significant factor in bringing about the opioid crisis in Cabell/Huntington:

- Mr. Rafalski admitted that he could not opine as to "whether Rite-Aid helped cause the opioid crisis in Huntington and Cabell County." 5/27 Tr. at 27:14–28:11. If Plaintiffs' own expert cannot opine that Rite-Aid itself—which was responsible for 2/3 of its total opioid distributions as a self-distributor, 5/11 Tr. (McCann) at 21:8–21—helped cause the opioid crisis in Cabell/Huntington, then he necessarily cannot opine that McKesson's minority fraction of shipments to Rite-Aid helped cause the opioid crisis.

- Mr. Rafalski expressly disclaimed any opinion about "whether diversion occurred at a pharmacy level" in Cabell/Huntington. 5/26 Tr. at 135:8–13. This specific admission by Mr. Rafalski that he could not identify any pharmacy in Cabell/Huntington that was engaging in diversion renders irrelevant his generic opinion that his flagged orders were "more likely than not" diverted.

- Mr. Rafalski admitted that he could not identify a single pill that was shipped by McKesson "that ended up filling a prescription that was dispensed other than in response to a licensed prescriber writing a prescription." 5/26 Tr. at 131:6–10. Absent evidence of such improper dispensing, Mr. Rafalski's testimony cannot possibly support Plaintiffs' suggestion that diversion was occurring at Rite Aid #968 (or any pharmacy).

In short neither the testimony of Mr. Rafalski nor any other record evidence establishes that diversion was occurring at Rite Aid #968 (or any other Rite Aid serviced by McKesson in Cabell/Huntington). Plaintiffs' lengthy discussion about Rite Aid thus provides no impediment to McKesson's motion for judgment.

Custom Script. Plaintiffs' discussion of Custom Script—the only other retail pharmacy in Cabell/Huntington serviced by McKesson that is discussed in the Opposition—likewise fails to provide any basis for denying McKesson's motion for judgment.

Custom Script was an independent compounding pharmacy that McKesson briefly serviced almost a decade ago—from 2010 to 2013. 5/25 Tr. (Ashworth) at 234:3–6. Plaintiffs again rely

on bare volume allegations that cannot prove their case. Plaintiffs' only evidence is that, in 2011, Custom Script received approximately 13,000 oxycodone dosage units per month from McKesson—which is higher than McKesson's average monthly shipments in Cabell/Huntington for the time period 2006–2014.[8] Opp. at 17. Even putting aside the obvious issue of staleness given that these shipments occurred a decade ago, Plaintiffs cite no record evidence even suggesting that this bare fact is itself evidence of wrongdoing or unreasonableness—nor could they.[9]

Plaintiffs next point to the fact that "Custom Script's controlled substance to prescription ratio consistently remained at or above 90%" as supposed evidence of wrongdoing. Opp. at 16-17. In so arguing, Plaintiffs rely on testimony from Mr. Oriente that a purchase ratio of 90% controlled substances would lead to termination for a ***typical*** retail pharmacy, but they ignore his further explanation that he would need to investigate "the[] [pharmacy's] business model" and "compare them to other customers to see why are they different." 5/25 Tr. (Oriente) at 142:24–143:21; *see also* 5/25 Tr. (Ashworth) at 249:15–22 (testifying that he could not state a "the right

[8] The figures that Plaintiffs cite for Custom Script are also cherry-picked: they compare (1) McKesson's shipments to Custom Script for 2011 to (2) McKesson's average monthly pharmacy distribution for all Cabell/Huntington customers for the period of 2006–2014. When adjusted to the same 2006–2014 time-period, Custom Script's average would be 4,083—an amount *lower* than the average calculated by Plaintiffs. *See* Trial Ex. P-44744_002 (total distribution of 441,000 for period from 2006–2014). This adjustment shows why use of such cherry-picked numerical comparisons is of no value in proving actionable conduct.

[9] Moreover, Plaintiffs' claim that McKesson's overall shipments of oxycodone to Custom Script over time amounted to 441,000, *see* Opp. at 19, is based on a misreading of a document created by their own expert, Dr. Craig McCann. The document shows that Custom Script received 441,000 in total shipments of oxycodone from "*All Sellers*" for the period from 2006 to 2014—six years longer than the period when it was serviced by McKesson. *See* Trial Ex. P-44744_002. This total includes significant shipments from non-party distributors, such as Quest Pharmaceuticals, which was responsible for "40 percent" of oxycodone shipments and "65 percent" of hydrocodone shipments to Custom Script in 2010 alone. 5/11 Tr. (McCann) at 188:16–22, 189:6–13.

percentage or the wrong percentage" for a purchase ratio, since it "depends on other factors; what kind of business").

Plaintiffs also entirely ignore the record evidence showing that McKesson ***did*** investigate Custom Script and determine that its 90% ratio was not indicative of diversion in light of its unique business model. Specifically, and as explained in McKesson's opening brief, Custom Script was a specialty compounding pharmacy in Barboursville that received a majority of its products from other raw material distributors. *See* Mem. at 10–11; *see also* Trial Ex. P-13284 at 7, 10 (diligence questionnaire stating that "this pharmacy's focus is compounding," and listing two "bulk powder" distributors as Custom Script's primary suppliers); *id.* at 18 (record of diligence investigation noting that Custom Script's purchase "volume [is] so low his % is an anomaly").[10] This unusual business model, as Mr. Oriente himself testified, provides a complete and benign explanation for Custom Script's seemingly anomalous 90% ratio. *See* 5/25 Tr. (Oriente) at 142:24–143:21 (testifying that a higher ratio would not be problematic if the pharmacy were engaged in "specialty compounding"). Plaintiffs do not cite any contrary evidence calling any of this into question.

Plaintiffs next take issue with the fact that certain diligence paperwork relating to a 2010 threshold change request could not be located and produced to Plaintiffs in 2019. Opp. at 15–16. But Plaintiffs' own expert, Mr. Rafalski, admitted that there no "record retention requirement under law for … diligence files," and that it is possible certain files simply "weren't kept" at the time that this litigation commenced. 5/26 Tr. at 269:21–25; 5/27 Tr. at 12:23–13:6. And the fact

[10] The fact that Custom Script was a compounding pharmacy also explains why Plaintiffs' suggestion that its distributions were high in light of Barboursville's small population, *see* Opp. at 18–19, is disingenuous: its primary customer base was healthcare providers like the Hospice of Huntington, not individuals. 5/25 Tr. (Ashworth) at 235:16–20 (explaining that as a compounding pharmacy, Custom Script "wouldn't have the normal retail traffic"); *id.* 237:18–238:23 (Custom Script serviced the Hospice of Huntington and an oncology clinic).

that some hard-copy paperwork may have been misplaced is particularly unsurprising given that McKesson stopped servicing Custom Script in 2013. *See* 5/25 Tr. at 152:2–6 (Mr. Oriente testifying that he was not aware of any policy requiring that "if you have a former customer … you keep their [Controlled Substances Monitoring Program ("CSMP")] file for all time").[11]

Plaintiffs further observe that Custom Script's customers included two prescribers (Dr. Fisher and Dr. Webb) identified as "outliers" by Plaintiffs' expert Lacey Keller. Opp. at 17. As explained in Defendants' Reply Memorandum in Support of Judgment on Partial Findings Regarding Proximate Causation, however, Plaintiffs' outlier prescriber evidence is irrelevant because (1) Ms. Keller disavowed any testimony that the prescriptions written by the outlier prescribers she identified were medically unnecessary, 6/15 Tr. at 165:16-22; *id.* at 191:15–19 ("It's just a mathematical calculation."); (2) volume alone cannot be used to determine whether a doctor is prescribing inappropriately; and (3) Defendants do not have the ability or role of second-guessing the prescribing decisions of doctors. *See* Defs.' Proximate Causation Reply at 22–25. Nor does the fact that these two physicians were subject to disciplinary proceedings before the West Virginia Board of Medicine ***years after they appeared in McKesson's diligence materials***

[11] In any case, there is ample record evidence to support the appropriateness of each of McKesson's diligence decisions and actions related to Custom Script. Plaintiffs admit that McKesson increased Custom Script's monthly threshold for oxycodone based on a threshold change request form ("TCR") received from the store on October 7, 2010. *See* Opp. at 16. In that TCR, Custom Script explained that it was expanding beyond "compounding products" to service prescriptions with Cabell Huntington Hospital's oncology clinic, the Hospice of Huntington, and two local pain management practices. Trial Ex. P-13714; *see also* 5/25 Tr. (Ashworth) at 237:18–238:23. After conducting diligence, a McKesson Director of Regulatory Affairs approved the request two days later, on October 10. Trial Ex. P-13712 (McKesson internal tracking form showing that TCR was "[d]one per DCM/TCR/AM/DG," where "DG" is the initials of the employee approving the request); *see also* 5/25 Tr. at 75:9–22 (Mr. Oriente testifying that each TCR was approved by "one of the four DRAs"). McKesson continued to monitor Custom Script's threshold and lowered that threshold when it observed that Custom Script's monthly purchasing had declined. Trial Ex. P-13284 at 18 ("Thresh[old] 30,500 never ordered 6,000 so lowered 3.25.13.").

indicate any diligence failures on the part of McKesson. 6/15 Tr. (Keller) at 189:5–10 ("I'm not offering the opinion that [a distributor] could see into the future.").[12]

* * *

In short, Plaintiffs have failed to come forward with ***any*** evidence that McKesson unreasonably failed to monitor and take appropriate actions with respect to any of its handful of pharmacy customers in Cabell/Huntington. Plaintiffs have also failed to come forward with ***any*** concrete evidence that a single prescription opioid medicine delivered by McKesson to a pharmacy in Cabell/Huntington was ever improperly dispensed by that pharmacy. Where such diversion was occurring—such as at the A-Plus Care Pharmacy in Barboursville—it was detected by law enforcement and is reflected in the evidentiary record.[13] The absence of any comparable evidence relating to any McKesson-serviced pharmacy is itself fatal to Plaintiffs' claims against McKesson. Indeed, even if Plaintiffs had proven that McKesson's diligence was deficient (they have not), that failure could not have substantially contributed to the opioid crisis in Cabell/Huntington in the absence of evidence of wrongdoing on the part of the customer to whom McKesson delivered the

[12] Plaintiffs' Opposition misstates the facts regarding Dr. Webb. Plaintiffs claim that Dr. Webb "faced a license suspension for improper opioid prescribing years before" appearing in Custom Script's diligence files, Opp. at 17 & n.75, but in fact his license was not suspended until four years *after* appearing in McKesson's Custom Script diligence files and three years *after* McKesson ceased doing business with Custom Script. *See* Trial Ex. P-13284 (diligence document identifying Dr. Webb in 2013); 6/15 Tr. (Keller) at 181:22–24 (Ms. Keller testifying that Dr. Webb surrendered his license in 2017).

[13] A-Plus Care Pharmacy, which was shut down by law enforcement in 2014, was "a major source of supply for pharmaceutical diversion to the tri-state area and beyond." *See* Trial Ex. P-41220 (HPD 2014 Annual Report) at 20. Indeed, according to the Huntington Police Department's Annual Report, A-Plus Care Pharmacy was responsible for *97%* of the diverted prescription opioid pills seized in 2014. *Id.*; *see also* 5/21 Tr. (Lemley) at 256:6–10. McKesson did not service the A-Plus Care Pharmacy. 5/12 Tr. (McCann) at 27:6–13 ("Q. A-Plus Care Pharmacy did not receive any shipments from … McKesson; correct? A. Correct.").

medicines. Because Plaintiffs have no such evidence, McKesson is entitled to judgment on partial findings.

II. PLAINTIFFS' RELIANCE ON EVIDENCE REGARDING PHARMACIES OUTSIDE CABELL/HUNTINGTON IS IRRELEVANT AND UNAVAILING.

Unable to prove causation from McKesson's distributions to its handful of pharmacy customers in Cabell/Huntington, Plaintiffs' Opposition focuses largely on cherry-picked examples of McKesson's distributions to various pharmacies located far outside Cabell/Huntington. Indeed, while Plaintiffs only ever discuss two McKesson pharmacies located in Cabell/Huntington, they discuss twice as many McKesson-serviced pharmacies located elsewhere in West Virginia—as far as 100 miles away. Their reliance on cherry-picked evidence regarding these extra-territorial pharmacies in unavailing for two fundamental reasons.

First, as explained above, volume evidence alone is not sufficient to establish unreasonableness. And there is nothing remotely surprising about the fact that Plaintiffs can identify a small number of pharmacies in West Virginia (out of McKesson's thousands of customers) that ordered an above-average number of prescription opioids—indeed, it is a mathematical certainty that some pharmacies will be above-average.[14] Because Plaintiffs say

[14] For example, Plaintiffs reference McKesson's distributions to a Sav-Rite Pharmacy in Mingo County, West Virginia between 2006 and 2007. Opp. at 20 & n.97. In support of this reference, Plaintiffs cite deposition designations that are subject to outstanding objections and have not been admitted into the record. These designations consist of Plaintiffs' counsel reading hearsay statements from a letter sent to McKesson by the U.S. House of Representatives, Committee on Energy and Commerce ("E&C Committee"), which itself quotes hearsay news articles. *See* Trial Ex. P-28144. Plaintiffs' Opposition shows that they are seeking to use these designations and the letter for their underlying truth, and both should be excluded. Notably, the Court has already excluded a report drafted by the E&C Committee's Majority Staff, *see* 5/18 Tr. 7:16–19, and Plaintiffs successfully objected to the admission of a similar letter on this basis, *see* 7/12 Tr. at 131:19–132:3 (Mr. Farrell objecting because "this is one of the documents that gives rise to the Energy and Commerce Report which you have excluded"). Even if considered, however, Plaintiffs offer no explanation as to why shipments from 13 years ago to a pharmacy 100 miles away would be relevant to their forward-looking abatement case.

absolutely nothing about these extra-territorial pharmacies other than that McKesson's distributions to them were above average, the evidence is simply irrelevant.

Second, as this Court has held, evidence regarding McKesson's allegedly wrongful shipments to pharmacies located outside Cabell/Huntington is irrelevant to this case in the absence of a "demonstrable nexus" between those distributions and any diversion in Cabell/Huntington. *See* ECF No. 1297 at 10. Plaintiffs glibly assert that McKesson's distributions to these pharmacies "undoubtably [sic] contributed to diversion in Cabell/Huntington," Opp. at 20, but they cite no record evidence in support of that assertion—because there is none. *See also* Defs.' Proximate Causation Reply at 16–22.

Especially under these circumstances, the Court should reject Plaintiffs' invitation to impose liability on McKesson for alleged wrongdoing that occurred outside of Cabell/Huntington. If McKesson improperly distributed prescription opioids in Mingo County (or in Florida), those are matters that can and should be addressed in the separate lawsuits brought against McKesson by Mingo County (and the State of Florida)—not in this lawsuit. Any other conclusion would result in the untenable and patently unfair result that a distributor could be held liable in every state and county across the entire nation for alleged wrongdoing in a single jurisdiction.

III. PLAINTIFFS' GENERALIZED EVIDENCE REGARDING MCKESSON'S ALLEGED SOM FAILURES IS IRRELEVANT AND UNAVAILING.

Plaintiffs' Opposition is largely an effort in misdirection. As explained above, it is Plaintiffs' burden to prove that wrongful distributions by McKesson to pharmacies in Cabell/Huntington were a substantial factor in causing opioid-related harms in Cabell/Huntington. Unable to do that, Plaintiffs instead devote the lion's share of their brief to discussing alleged deficiencies in McKesson's suspicious order monitoring systems. But the evidence cited by Plaintiffs is largely (if not entirely) irrelevant to the issue currently before the Court.

In order to prove that McKesson's wrongful conduct was a substantial factor in bringing about the opioid crisis in Cabell/Huntington, it is not enough for Plaintiff to show—in some abstract sense—that McKesson's SOM systems were less than perfect. Instead, Plaintiffs have to show (at a minimum) that McKesson's alleged failures actually led to the diversion of a significant amount of prescription opioids in Cabell/Huntington. For this fundamental reason, the Court need not parse through each category of evidence that Plaintiffs throw against the wall in their Opposition and determine whether, for example, McKesson could have done a better job reporting suspicious orders to DEA or could have cut off a couple of Internet pharmacies at the turn of the century a little faster. In other words, because Plaintiffs lack evidence that any of the purported SOM deficiencies they identify actually had an impact in Cabell/Huntington, the evidence is irrelevant and need not be considered by the Court ***at all***.

Moreover, Plaintiffs' evidence is stale. McKesson's opening brief highlighted the complete absence of ***any concrete evidence*** of any deficiencies in McKesson's SOM program in or after 2013. Mem. at 36–38. Plaintiffs' Opposition makes no attempt to contest this fact. Indeed, Plaintiffs entirely ignore McKesson's post-2013 program. Accordingly, Plaintiffs concede that McKesson's current program is not in any way deficient, including as it has been applied to customers in Cabell/Huntington ***for at least the last eight years***.

In a forward-looking abatement case, Plaintiffs' complete failure to identify any issues with the compliance program that has been operated by McKesson for almost a decade is a stunning concession. Plaintiffs, in effect, ask the Court to find that McKesson's operation of its former SOM programs, which were modified ***nearly a decade ago*** (or more), somehow contributed to Cabell/Huntington's current illegal drug problem. No record evidence supports such a finding.

For these two threshold reasons, the Court need not read any further. But Plaintiffs' evidence—much of which consists of objectionable deposition designations and exhibits that were not subject to live trial testimony and have not yet been admitted[15]—also fails on its own terms, for the reasons explained below.

A. Pre-2008 SOM Programs

The bulk of Plaintiffs' criticisms relate to the period before 2008, when McKesson introduced a new SOM system. This 13-year-old (or more) evidence is stale, especially in a forward-looking abatement case. In any event, Plaintiffs fail to overcome McKesson's showing that its pre-2008 systems fully complied with contemporaneous DEA guidelines and industry standards. *See* Mem. at 16–26.

"Section 55" Algorithm to Identify Suspicious Orders. Plaintiffs first take issue with the algorithm that McKesson used to identify suspicious orders under its pre-2008 SOM program ("Section 55"), but fail to acknowledge that this algorithm was derived based on DEA guidance. Opp. at 3. Specifically, under Section 55, McKesson identified suspicious orders by using a "three times monthly average for Schedule[] II and III" prescription opioids. 5/25 Tr. (Michael Oriente) at 44:2–14; *see also* Trial Ex. MC-WV-00451 at 47 (Section 55). This three-times criteria for identifying suspicious orders was identical to another monitoring system that the DEA had reviewed. 5/25 Tr. at 50:3–51:18 (Mr. Oriente testifying as to his understanding that Section 55 was "based on DEA approved guidelines"). McKesson's Section 55 Manual includes a copy of the letter that the DEA sent after reviewing this three-times modifier, which stated that this algorithm would "provide effective customer verification and suspicious and/or excess order

[15] Plaintiffs' deposition designations and accompanying exhibits were submitted subject to McKesson's objections, and therefore are not yet part of the record. For purposes of responding to this motion, McKesson addresses this evidence, but does not waive its objections to admission.

monitoring" and "appear[s] appropriate for implementation." Trial Ex. MC-WV-00451 at 204–205. Based on this letter, McKesson informed its employees that "these guidelines have been accepted by DEA" and "compliance with them is mandatory." *Id.* at 46.

Relying on the testimony of Mr. Rannazzisi, Plaintiffs argue that the DEA does not approve SOM programs. Opp. at 21 (incorporating ECF No. 1471 at 24–25). But Mr. Rannazzisi began work at the Office of Diversion Control in 2005. As to the pre-2005 time period, Plaintiffs cite only Mr. Rannazzisi's hearsay statements about what he was purportedly "told" when he joined the office. *See* 6/9 Tr. at 220:9–16, 238:4–7. Such statements were admissible at trial to explain Mr. Rannazzisi's belief about DEA's policy, but they are not evidence of the ***truth*** of that belief. Similarly, Plaintiffs cite Thomas Prevoznik's testimony about DEA's current practice, *see* Prevoznik Dep. Tr. at 752:14–15 ("DEA doesn't endorse the systems"), but ignore his acknowledgement that ***DEA's prior practice did involve approving SOM systems***, *see id.* at 1135:2–6 (reviewing 1996 DEA correspondence and agreeing that "[t]hey're approving the system").

In any event, the relevant question is not whether DEA formally "approved" McKesson's Section 55 program and its algorithm. Rather, the question is whether it was reasonable for McKesson to use that algorithm at the time. And DEA's express statement that the system "provide[s] effective customer verification and suspicious and/or excess order monitoring" and "appear[s] appropriate for implementation," Trial Ex. MC-WV-00451 at 204–205, is not only relevant to that question—it is dispositive.

No Blocking of Suspicious Orders. Plaintiffs' principal criticism of McKesson's pre-2008 system is that it failed to comply with a purported legal duty not to ship orders identified as "suspicious." *See, e.g.*, Opp. at 26–27. But that argument fails for at least three separate reasons.

First, neither the CSA nor its implementing regulations impose any duty on wholesale distributors not to ship suspicious orders. *See* Defs.' Mem. of Law in Opp. to Pls.' Mot. for Partial Summary Judgment Concerning Defs.' Statutory and Regulatory Duties (ECF No. 1079). Rather, the regulations merely set forth provisions—largely for the physical handling of controlled substances while they are in a distributor's custody and control—to be used as part of the DEA's registration process. *Id.* at 5–15. And they clearly do not set forth an unspoken duty not to ship suspicious orders. *Id.* at 5–12; *see* 21 C.F.R. § 1301.74(b) (only provision of regulations that mentions suspicious orders; no reference to blocking or not shipping such orders).[16]

Second, the record is clear that the DEA did not revise its sub-regulatory guidance and advise distributors not to ship suspicious orders for the first time until the second half of 2007. *See* Mem. at 26–29; *see also United States v. $463,497.72*, 853 F. Supp. 2d 675, 682 (E.D. Mich. 2012) (identifying September 2007 as when DEA "told distributors" about its "***new interpretation***" of the suspicious order regulation); *Masters Pharmaceuticals, Inc. v. DEA*, 861 F.3d 206, 222 (D.C. Cir. 2017) (identifying the July 2007 *Southwood* administrative decision as the place where DEA "***first articulated***" its revised guidance).[17] Plaintiffs do not meaningfully dispute that this "do not ship" guidance represented a shift in DEA policy, but attempt to argue that the changed guidance was issued in 2005. Opp. at 12. They are mistaken.

Plaintiffs suggest that DEA informed McKesson of its revised guidance at a 2005 meeting, *see* Opp. at 22, but the record contradicts that assertion. The 2005 presentation cited by Plaintiffs

[16] Notably, this Court previously *denied* Plaintiffs' motion for summary judgment asking the Court to hold that Defendants have a duty under the CSA not to ship suspicious orders. *See* Order Denying Pls.' Mot. for Partial Summ. J. Concerning Defs.' Statutory and Regulatory Duties (ECF No. 1291).

[17] Unless otherwise noted, all emphases added.

states only that "[r]reporting a suspicious order to DEA does NOT relieve the distributor of the responsibility to maintain effective controls against diversion." Trial Ex. P-12805 at 10. Nowhere in the presentation or the associated cover memo does the DEA say that all orders identified as suspicious should be blocked.[18]

Plaintiffs next rely on the testimony of Mr. Rannazzisi to suggest that this guidance was provided in 2005. Opp. at 21–22. But on cross-examination, Mr. Rannazzisi was forced to admit that "before 2006 and 2007 [he had] no firsthand knowledge about whether … standard practice in the industry [was] to file Suspicious Order Reports while continuing to ship product." 6/9 Tr. (Rannazzisi) at 14:19–15:10. And Plaintiffs' DEA expert, Mr. Rafalski—who did have first-hand knowledge about this period—confirmed "that there was no do not ship requirement before 2007." 5/26 Tr. at 252:14–19.

Third, McKesson's Director of Regulatory Affairs, Michael Oriente, testified that—at all times, including during the pre-2008 period—McKesson reviewed orders prior to shipment and used "a manual process" to block any orders that McKesson determined were likely to be diverted. 5/25 Tr. (Oriente) at 9:2–12, 48:4–14; *see also* Trial Ex. MC-WV-00451 at 51 ("[O]rder fillers … are expected to report to management any unusual purchase request before orders are filled"). Accordingly, the record is devoid of any evidence that McKesson knowingly shipped orders that were likely to be diverted during the pre-2008 time-period (or thereafter).

Suspicious Order Reporting. Plaintiffs next criticize two aspects of McKesson's suspicious order reporting practices during the pre-2008 time-period. First, they fault McKesson

[18] McKesson Director of Regulatory Affairs, Gary Hilliard, who attended the presentation, explained during his deposition that other measures to maintain effective controls included, *inter alia,* license validation checks, ARCOS reporting, theft and loss reporting, physical security measures such as vaults and cages, and additional paperwork to track Schedule II purchases. *See* Gary Hilliard Dep. Tr. at 95:24–97:20.

for reporting suspicious orders retroactively. Opp. at 27. And, second, they argue that McKesson's Washington Courthouse Distribution Center failed to report any suspicious orders during this time-period. Opp. at 28. Neither criticism has merit.

Prior to 2009, McKesson utilized a "DU-45" report to submit suspicious orders to the DEA on a daily and monthly basis. *See* Trial Ex. P-42747; Trial Ex. MC-WV-02143. Plaintiffs complain that DU-45s were only ever submitted "retroactive[ly]." Opp. at 27. But—even if that were true[19]—it would do nothing to establish unreasonableness on the part of McKesson. Rather, for the unrebutted reasons explained in McKesson's opening brief, it was common practice at the time—and fully accepted by DEA as compliant—to send suspicious order reports to DEA only after the order had shipped. *See* Mem. at 17–20.

Plaintiffs' suggestion that the Washington Courthouse Distribution Center failed to report any suspicious orders during this time-period is also misplaced. The sole apparent basis for Plaintiffs' assertion is the fact that McKesson did not produce in discovery any DU-45 reports from Washington Courthouse for this time-period. But the inference Plaintiffs draw from this fact is belied by the weight of the record evidence. The undisputed trial testimony establishes that (i) DEA did not impose any mandatory retention period for such records, and (ii) McKesson's retention period for these reports was two years. 5/27 Tr. (Rafalski) at 13:12–17; 5/25 Tr. (Oriente) at 43:18–44:1. Thus, the absence of such reports in McKesson's document productions simply does not support the inference that the reports were not made. Moreover, Mr. Oriente's trial

[19] Plaintiffs' suggestion (unadorned by citation to the record) that DU-45 reports were invariably sent after the fact is also belied by the evidence. Section 55 of McKesson's Drug Operations Manual states that the "Daily Controlled Substance Suspicious Order Warning Report … can be faxed to your local DEA office *before the order is shipped*." Trial Ex. MC-WV-00451 at 48.

testimony establishes that DU-45 reports were created and sent by "***each*** distribution center." 5/25 Tr. at 43:11–17.[20]

Generic Hydrocodone Reporting. Plaintiffs' assertion that "McKesson was not monitoring the sale of generic opioids," Opp. at 3–5, is disconnected from the record evidence. McKesson's opening brief laid out substantial testimony and exhibits showing that Mr. Rannazzisi's speculation regarding allegedly systemic issues with respect to the reporting of generic hydrocodone in 2006 was incorrect—as Mr. Rannazzisi himself was forced to acknowledge on cross-examination. Mem. at 22–24. Rather than address this evidence, Plaintiffs simply ignore it.

As set forth in McKesson's opening brief, Mr. Rannazzisi (who was the only witness to testify on this issue) admitted that:

- McKesson submitted ARCOS reports to the DEA that included ***all*** generic hydrocodone products. 6/9 Tr. at 61:16–62:6.
- McKesson submitted DU-45 reports to the DEA that included ***all*** generic hydrocodone products. 6/9 Tr. at 68:19–22; *see also* Trial Ex. MC-WV-02134.
- Mr. Rannazzisi had "no information" that the omission of generic hydrocodone from an *ad hoc* report prepared for the Lakeland, Florida distribution center "was a chronic issue" or impacted any distribution center other than Lakeland. 6/8 Tr. at 239:19–22.

[20] Plaintiffs also assert that DU-45 reports were not in the correct format because they reported "excessive purchases." Opp. at 3, 27. This argument completely ignores the evidence in McKesson's opening brief establishing that so-called "excessive purchase reports" were commonly accepted by the DEA prior to 2007. *See* Mem. at 17–18, 27 n.21. Plaintiffs instead rely on testimony from Mr. Rannazzisi who proclaims that "excessive purchase reports" were not *useful*. *See* Opp. at 3. Whatever Mr. Rannazzisi's after-the-fact assessment of the utility of these reports might be, in September 2006—at the time that he now claims distributors were submitting the wrong format—Mr. Rannazzisi wrote a letter to distributors stating that "the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion." Trial Ex. P-00033 at 2.

In short, the clear weight of the record evidence belies Plaintiffs' suggestion that McKesson failed (15 years ago) to report to DEA suspicious orders for generic hydrocodone placed by its customers.

Florida Internet Pharmacies. Plaintiffs also point to a DEA administrative order to show cause, issued in April 2006, in which Mr. Rannazzisi asserted that McKesson shipped a high-volume of prescription opioids to a pharmacy in Florida over a four-month period in late 2005. Opp. at 4 (citing Trial Ex. P-00016). Plaintiffs fail, however, to address any of the arguments about this issue in McKesson's opening brief. *See* Mem. at 20–22. Nor do they explain how this stale, 15-year-old evidence could possibly be relevant to their forward-looking abatement case.

Most notably, Plaintiffs fail to grapple with the fact that McKesson took prompt action to cut off each of the few Florida-based Internet pharmacies identified by DEA in late 2005. Trial Ex. Trial Ex. DEF-WV-01557 at 3 ("[A]s of January 9th, 2006, these pharmacies have been terminated by McKesson."). This was two years prior to Congress passing legislation that prohibited the operation of internet pharmacies. *See* 6/8 Tr. at 215:12–20 (Mr. Rannazzisi conceding that he was "not aware of any shipments" by any distributor to any internet pharmacy since "2008 [when] Congress passed" the Ryan Haight Act). Nor do Plaintiffs dispute that DEA continued to license these pharmacies for nearly a year after McKesson cut them off. 6/8 Tr. (Rannazzisi) at 227:16–228:4 (conceding that the pharmacies remained licensed by the DEA and were able to receive "close to … 10 million pills" from other distributors after McKesson took action).

In any event, there is no evidence that any of the pills distributed over a decade ago to these pharmacies in Florida ever entered Cabell/Huntington. Mem. at 21; *see also* 6/8 Tr. (Rannazzisi) at 216:17–21. Accordingly, this evidence lacks a "demonstrable nexus" to Cabell/Huntington.

The Lifestyle Drug Monitoring Program ("LDMP"). Plaintiffs' quibbles about McKesson's Lifestyle Drug Monitoring Program ("LDMP")—which was only in place for 11 months in 2007, 5/25 Tr. at 59:11–60:1—are also stale and do nothing to establish unreasonableness.

First, Plaintiffs complain that the LDMP monitored only four controlled substances. Opp. at 5. But McKesson continued submitting DU-45 reports for all prescription opioids throughout the time that it used the LDMP. *See* 5/25 Tr. (Oriente) at 43:1–4. And of the four controlled substances to receive additional monitoring, two were hydrocodone and oxycodone—the only two drugs for which Plaintiffs have offered any evidence at trial. *See* Trial Ex. P-00098. That the LDMP did not add additional monitoring for other drugs is, therefore, irrelevant.

Second, Plaintiffs point out that the LDMP did not include an automated blocking system for all orders above a threshold. Opp. at 6. The absence of such a blocking system, however, is explained by the fact that—at the time of LDMP's implementation—there was no expectation that distributors block suspicious orders. *See supra* pp. 18–20. The LDMP, moreover, was only a temporary program—and was replaced in short order by McKesson's 2008 CSMP program, which undisputedly ***did*** automatically block all orders identified as suspicious. *See* 5/25 Tr. (Oriente) at 62:25–63:3 ("[S]ystematic blocking started in May, 2008").

Third, Plaintiffs point to a handful of McKesson internal audit reports regarding the LDMP. Opp. at 5–6. Far from evidencing a lack of attention to compliance issues, however, these audits illustrate that McKesson was committed to testing the LDMP nearly immediately upon implementation, so as to proactively identify and correct the sort of issues that inevitably occur with the adoption of any new system. *See* Trial Ex. P-00098 at 1 (July 27, 2007 audit report, noting

that the LDMP was "fully implemented in all of the DCs as of June 1, 2007"); Trial Ex. P-012937 (August 17, 2007 audit); Trial Ex. P-012938 (August 18, 2007 audit).

2008 Settlement Agreement. As set forth in McKesson's opening brief, Plaintiffs cannot use McKesson's 2008 settlement as evidence of wrongdoing, as such reliance is expressly prohibited by Federal Rule of Evidence 408. Mem. at 25. Nonetheless, that is precisely what Plaintiffs attempt to do. Opp. at 4, 23. In fact, Plaintiffs rely extensively on the 2008 Settlement to claim that "McKesson's failure to maintain controls against diversion contributed to … wide-scale diversion." *Id.* at 23. But in addition to being stale, the "evidence" that Plaintiffs rely on for this claim is a portion of the Settlement Agreement that is titled "Conduct ***Alleged*** to have Occurred," *see* Trial Ex. P-00016 at 188, as well as the agreement's preamble setting out DEA's allegations, *id.* at 202.[21] Critically, the 2008 Settlement expressly states that "[t]his agreement is neither an admission by McKesson of liability or of any allegations made by the DEA in the Orders and investigation…." Trial Ex. P-23733 at 2. As such, the DEA's allegations within this agreement are not proof of anything, and they certainly are not proof of actionable conduct in Cabell/Huntington. That is particularly true in the context of Plaintiffs' forward-looking abatement case, where each of the allegations is from at least a dozen years ago. And, even if the Court were to consider the allegations that Plaintiffs cite in the 2008 Settlement Agreement, none of those allegations relate to the Washington Courthouse Distribution center that serviced Cabell/Huntington. *See* Mem. at 25.

[21] For purposes of their Opposition, Plaintiffs cite to a copy of the 2008 Settlement Agreement that is part of a larger document, rather than the separate version used with live witnesses during trial. For consistency, McKesson has done the same when referencing Plaintiffs' use of this document.

B. 2008–2013: Controlled Substance Monitoring Program

Plaintiffs also point to several alleged deficiencies in McKesson's Controlled Substance Monitoring Program, which was implemented in 2008 in response to changed DEA guidance regarding suspicious order monitoring. Opp. at 7–15, 22–29. Each of Plaintiffs' claimed errors relies on mistakes of law, mistakes of fact, or both. More fundamentally, however, each of the claimed errors is again divorced from any showing that it resulted in harm ***in Cabell/Huntington.***

Suspicious Order Reporting. Plaintiffs criticize McKesson for failing to ***report*** certain suspicious orders to DEA beginning in 2009, citing McKesson's 2017 settlement agreement with DEA and related correspondence from DEA. *E.g.*, Opp. at 28 (citing, *inter alia*, P-42814[22]). But they offer no real response to McKesson's showing that (1) it began blocking ***all*** suspicious orders in 2008, Mem. at 28; 5/25 Tr. (Oriente) at 9:8–12, and (2) according to Plaintiffs' own witnesses, blocked orders cannot lead to diversion or cause any harm. Mem. at 36; *see also, e.g.*, 5/26 Tr. (Rafalski) at 208:10–12 ("***Not reporting the suspicious order to the DEA is not what causes diversion***."); 6/9 Tr. (Rannazzisi) at 13:25–14:5 (acknowledging that a blocked order "can't go downstream" and therefore "***can't be diverted***"). As such, any alleged reporting issues are wholly

[22] Trial Ex. P-42814 is a 2011 letter that was sent by a local DEA office in Columbus setting forth unproven allegations against McKesson. Plaintiffs assert that the letter "corroborate[s]" their claim that McKesson "fail[ed] to properly report suspicious orders." Opp. at 28 The Court, however, admitted the letter only for the limited purpose of notice, explaining that it was "not going to consider it for the truth." 5/24 Tr. at 224:11–17. Plaintiffs' attempt to disregard that limitation should be rejected.

In any event, McKesson quickly responded that it was reporting suspicious orders to the main DEA office in Washington DC. *See* Trial Ex. MC-WV-2158 (trial exhibit also introduced for the limited purpose of notice). Moreover, nothing in Trial Ex. P-42814 even remotely suggests that McKesson was not blocking all of the suspicious orders it received.

disconnected from Plaintiffs' claimed theory of harm, which relates to an oversupply of prescription opioids allegedly shipped to Cabell/Huntington.[23]

Plaintiffs also attempt to obfuscate the time period during which McKesson—based upon its understanding of DEA's reporting expectations—was reporting relatively fewer orders to DEA.[24] While it is true that the "Covered Time Period" for McKesson's 2017 DEA settlement was 2009–2017, the record makes clear that McKesson modified its suspicious order reporting methodology ***in 2013***, immediately after the DEA informed McKesson of the concerns that ultimately led to the settlement. 5/25 Tr. (Oriente) 126:2–8 (testifying that McKesson began reporting more in 2013 in response to the DEA, while "[f]ull blocking continued").[25]

"Dear Registrant" Letters. Plaintiffs assert that McKesson "ignore[d] … regulatory guidance" in the form of letters sent by the DEA to all registrants in 2006 and 2007. Opp. at 22

[23] Plaintiffs attempt to obscure this basic reality by asserting that "when suspicious orders were reported to DEA the agency investigated those orders." Opp. at 29. In addition to being irrelevant, however, that is also untrue. In 2019, the U.S. Department of Justice, Office of the Inspector General, issued a report that found that the DEA failed to maintain its SORS database by "includ[ing] all suspicious order reports provided to the DEA, thereby significantly impacting its usefulness." Trial Ex. DEF-WV-01597 at 36. The report also found that local DEA field staff frequently "could not locate" the suspicious order reports they received and "did not receive access to the SORS database until 2017." *Id.*

[24] Plaintiffs misconstrue a McKesson presentation to suggest that McKesson was underreporting suspicious orders in 2015. *See* Opp. at 28 & n.130. That presentation discusses orders "rejected" by McKesson for a reason unrelated to suspicious order monitoring—such as the item having being discontinued—and, due to that rejection, never proceeding the stage where the order would be compared against a customer's threshold. *See* Trial Ex. P-13296 at 8. It is difficult to conceive of a situation more removed from Plaintiffs' claimed harm than this sort of rejected order.

[25] While the Opposition proclaims—once more without citation to record evidence—that the 2017 Settlement Agreement included "orders … specifically in Cabell County," Opp. at 28, that evidence is nowhere in the trial record. Instead, Mr. Rannazzisi admitted that he did not know "if any of those orders or pharmacies [identified in the narrow "acceptance of responsibility"] are in Cabell/Huntington. 6/10 Tr. at 87:1–16.

(incorporating ECF No. 1471 at 28–32).[26] But they do not cite any evidence to support their assertion, and the record flatly contradicts it. As Plaintiffs acknowledge, the DEA issued a statement in its December 2007 letter regarding its expectation that distributors block and do not ship orders identified as suspicious. *See* ECF No. 1471 at 31–32 (citing Trial Ex. P-00032).[27] Within five months of that letter, McKesson had developed and implemented a new SOM program that applied automated blocking. 5/25 Tr. (Oriente) at 62:25–63:3 ("[S]ystematic blocking started in May, 2008"); *see also id.* at 55:12–24 (Mr. Oriente testifying that McKesson "started blocking all orders that exceeded [a] threshold" in 2008 "because of the guidance change" from DEA).

CSMP Thresholds. Plaintiffs argue that McKesson did not appropriately set and maintain thresholds under the CSMP. Opp. at 7–8. But the claim is unsupported by the evidence.[28]

Plaintiffs' main argument is that, because McKesson relied on historical distribution data to set initial thresholds, the thresholds were set too high.[29] But no trial witness—including Plaintiffs' SOM expert, Mr. Rafalski—ever testified that McKesson failed to set its thresholds appropriately when it implemented the CSMP in 2008. This lawyer argument—unsupported by expert testimony or any other competent evidence—cannot save Plaintiffs' claims.

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[26] In fact, the DEA letters are not *regulatory* guidance at all. Unlike regulations, the letters were not subject to notice-and-comment rulemaking and did not have binding effect. *See* Defs.' Mem. of Law in Opp. to Pls.' Mot. for Partial Summ. J. Concerning Defs.' Statutory and Regulatory Duties (ECF No. 1079) at 12–13; *see also Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418, 55,475 (DEA Sept. 15, 2015) ("[A] review of the letters shows that they were not intended to have binding effect….").

[27] The 2006 letter did *not* advise registrants not to ship suspicious orders. *See* Mem. at 27 n.22 (citing Trial Ex. P-00033).

[28] *See also supra* pp. 5–9 (discussing Plaintiffs' criticisms relating to chain pharmacies).

[29] Plaintiffs make the statement that past purchase data was drawn from a time period when "diversion was flourishing in McKesson supplied-pharmacies," Opp. at 8, but they do not cite any record evidence in support of the claim.

Plaintiffs next criticize McKesson for its prior practice of giving customers advance notice when their orders were approaching a threshold. Opp. at 8. But Plaintiffs ignore the fact that—even if a customer responded by requesting a threshold change—the customer would still have to satisfy the "whole threshold request procedure." 5/25 Tr. (Ashworth) at 219:9–18. In other words, a TCR form would still have to be reviewed, investigated, and approved by a McKesson Director of Regulatory Affairs in accordance with McKesson's normal diligence procedures before the customer's order level was adjusted. *See* 5/24 Tr. (Oriente) at 75:5–20 ("We would ask why, why do they need the increased, what's changed in their business.").

Plaintiffs' reliance on a handful of internal emails likewise fail to establish any actionable conduct on the part of McKesson. First, Plaintiffs point to a July 2012 email that they claim shows McKesson's "due diligence to support increased thresholds was insufficient." Opp. at 13 (citing Trial Ex. P-08761). But the email actually shows the opposite. In it, a McKesson Director of Regulatory Affairs, Tom McDonald, is reaching out to the sales team he works with to remind them that TCR forms "should be accompanied by specific examples of what is generating … growth." P-08761. He goes on to emphasize, ***"many of you do this very well. I appreciate your attention to detail."*** *Id.; see also* 5/25 Tr. (Oriente) at 164:19–165:1 (testifying that Directors of Regulatory Affairs "regularly reinforced" good habits to the sales team).

Another email highlighted by Plaintiffs tells a similar story. In it, a McKesson Director of Regulatory Affairs suggests to colleagues that they should "tighten up the process granting [threshold] increases," but also notes—in a section of his message that Plaintiffs omit—that McKesson "has gone to great lengths to vet each of our accts (ISMC and others) over time and put photos, search engine result screen prints, dispensing data, questionnaires, TCRs, Level 1 and interview notes on file." Trial Ex. P-12821 at 3. Far from evidencing a lack of attention, this

communication illustrates that McKesson's employees were proactively identifying areas for improvement while following rigorous diligence procedures. *See* 5/25 Tr. at 165:24–166:17 (Mr. Oriente explaining each type of documentation referenced in Trial Ex. P-12821).[30]

In short, Plaintiffs have failed to come forward with credible evidence that the CSMP was designed or implemented in an unreasonable manner.[31] Moreover, Plaintiffs do not make any effort to tie the alleged deficiencies in the CSMP to any diversion or harm in Cabell/Huntington. For example, the mere existence of a too-high threshold cannot cause harm unless a customer abuses that threshold to purchase prescription opioids and uses them for some purpose other than to fill a legitimate prescription.[32] But the record is devoid of any evidence that any of McKesson's customers in Cabell/Huntington were dispensing opioids inappropriately. Accordingly, even if the Court were to conclude that the CSMP was designed and implemented in a less than perfect manner, that would do nothing to show that these errors caused harm ***in Cabell/Huntington***—which is the bare minimum that Plaintiffs would need to show in order to withstand judgment.

Regulatory Affairs Staffing. Plaintiffs also point to a handful of emails in which Mr. Oriente and other Directors of Regulatory Affairs vented about their frustration at feeling

[30] An 2010 audit of the Washington Courthouse distribution center cited by Plaintiffs tells a similar story. *See* Opp. at 14 (citing Trial Ex. P-00115). The audit noted various errors related to paperwork retention. Trial Ex. P-00115 at 13–14. However, it also included an "action plan" to quickly correct these paperwork errors moving forward. *Id.* According to Mr. Oriente, McKesson's proactive internal audits are a way to "check the checker" in order to "enhance and improve McKesson's program." 5/25 Tr. at 146:24–147:10.

[31] The record, moreover, reveals that when McKesson implemented the CSMP, it presented the program to the DEA and expressly informed the DEA about the very policies that Plaintiffs now attack. *See, e.g.*, 5/25 Tr. (Oriente) at 103:3–24 (describing presentation to the DEA about the use of past purchase history to set thresholds); *id.* at 107:10–108:6 (describing presentation to the DEA about the provision of threshold warning reports); Trial Ex. P-42657 (DEA presentation).

[32] *See* 5/25 Tr. (Oriente) at 73:11–14 ("Q. Do you know one way or another whether simply because a customer has a threshold at a certain level they have to order up to that level? A. No. Most customers order below their threshold.").

overworked. Opp. at 8. While Plaintiffs cast these emails as evidence of a failure of McKesson's CSMP, that claim is unfounded. Mr. Oriente testified that while he (like many of us) certainly felt busy at times, he "continued to do [his] due diligence. It just meant longer hour days and sometimes working weekends." 5/25 Tr. 67:15–19. He further emphasized that when he did not have time to complete a threshold change request "[i]t would just take longer to get reviewed. It wasn't … approved with no review." 5/25 Tr. at 67:20–68:6. The Directors of Regulatory Affairs also received assistance from members of McKesson's operational staff in each of its 28 distribution centers. 5/25 Tr. (Oriente) at 68:16–69:7.

In any case, Plaintiffs' complaints about staffing are once more untethered from their theory of harm. Absent some showing that improper shipments entered Cabell/Huntington because of a staffing shortage, Plaintiffs' reference to stray emails (among the millions produced by McKesson in discovery) exhibiting workplace frustration is not sufficient to avoid judgment in favor of McKesson.

Letters From the DEA/DOJ. In a last-ditch effort to buttress their claims, Plaintiffs go outside the record and rely on four letters from the DOJ/DEA that the Court has not admitted—and should not admit—into evidence. Opp. at 24 & n.112. Each of these letters is fraught with hearsay allegations and was sent by the DEA/DOJ to McKesson during negotiations that resulted in the 2017 Settlement. As the Court has already observed, these letters were sent "in the context of negotiations" and are "the position of the … lawyers on one side." 5/24 Tr. at 105:21–23.

Plaintiffs' motion for reconsideration regarding these letters is currently before the Court. *See* ECF Nos. 1436, 1465. In that briefing, Plaintiffs advance the implausible argument that they only seek to use these letters to show "notice" to McKesson. But their Opposition puts the lie to that claim, as Plaintiffs repeatedly and exclusively cite the letters for the truth of the matters

asserted therein. *See* Opp. at 24 & n.112. The Court should therefore deny Plaintiffs' motion for reconsideration and decline to consider these letters.[33]

CONCLUSION

McKesson is entitled to judgment because Plaintiffs have failed to prove any actionable conduct on the part of McKesson that was a substantial factor in causing the opioid crisis in Cabell/Huntington.

[33] The Opposition likewise cites to portions of two documents—Trial Exs. P-16210 and P-12814—that the Court has *excluded* from the record. *Compare* Opp. at 25 n.116 (citing a quote by Mr. Rannazzisi in Trial Ex. P-12814 at 6), *with* 5/24 Tr. at 71:17–72:13 (excluding slide 6 in Trial Ex. P-12814 and stating that "the Court is not going to consider that one panel for anything"), *and compare* Opp. at 26 at n.120 (citing Trial Ex. P-16210) *with* 5/24 Tr. at 76:22–77:12 (excluding all but two pages of Trial Ex. P-16210, neither of which is the page used in Plaintiffs' Opposition). The attempt to place excluded evidence before the Court at his late juncture is highly prejudicial. McKesson requests that the Court decline to consider that portion of Plaintiffs' Opposition that relies on these exhibits.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on this 11th day of August, 2021, the foregoing REPLY MEMORANDUM IN SUPPORT OF MCKESSON'S MOTION FOR JUDGMENT ON PARTIAL FINDINGS REGARDING ACTIONABLE CONDUCT was served using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

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